



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,663	11/13/2003	Kuo-Hsiung Lee	5470-397	2599

7590 10/31/2005

Kenneth D. Sibley
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, NC 27627

EXAMINER

OWENS, AMELIA A

ART UNIT	PAPER NUMBER
----------	--------------

1625

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,663	LEE ET AL.	
	Examiner	Art Unit	
	Amelia A. Owens	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-20 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,6-12,22 and 23 is/are allowed.
- 6) ☒ Claim(s) 13 and 24 is/are rejected.
- 7) ☐ Claim(s) 14-20 and 25-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1625

DETAILED ACTION

1. Claims 4,5,21 have been canceled. New claims 22-28 have been added. Claims 1-3,6-20,22-28 are pending.

Claim Rejections - 35 USC § 102

2. The rejection of claim 1,4,11-13,19-20 rejected under 35 U.S.C. 102(b) is dropped as the claims have been canceled and/or amended.

Double Patenting

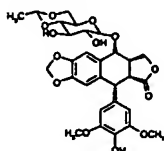
3. The rejection of claims 1-5,11-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over U.S. Patent No. 6566393 is dropped as a terminal disclaimer has been filed and accepted.

Claim Rejections - 35 USC § 112

4. Claims 13,24 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for lung cancer, stomach cancer, esophageal cancer, colon cancer, breast cancer, liver cancer, prostate cancer, Kaposi's sarcoma, testicular cancer, ovarian cancer, endometrial cancer, does not reasonably provide enablement for skin cancer, central nervous system cancer and cancer in the general sense. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicants' comments have been considered but are not persuasive in view of the following.

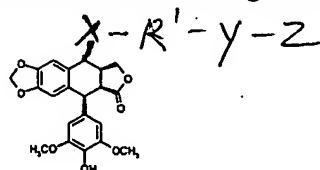
The state of the art is that etoposide has been used to treat a variety of neoplasms such as Kaposi's, testicular cancer, lymphoma, leukemia, and small-cell lung. See abstract Kobayashi et al, Pharmacodynamics and long-term toxicity of Etoposide, PMID: 8070030. See also abstract Sinkule, Etoposide: a semisynthetic epipodophyllotoxin. Chemistry, pharmacology, pharmacokinetics, adverse effects and use as an antineoplastic agent. PMID: 6326063. See also Atienza et al, Phase II study of oral Etoposide of patients with advanced breast cancer. PMID: 8625074. See also Zhi, High-grade endometrial stromal sarcoma in a 10-year-old girl: case report. PMID: 9849013.

Etoposide has the following formula:

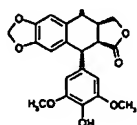


Art Unit: 1625

The claimed compounds have the following formula:



Structurally similar compounds would be expected to have the same activity. Clearly compounds having the core structure depicted below have been shown to have anti-cancer activity against a variety of cancers. Thus, the claimed compounds would be expected to have the same activity as the prior art compounds.



However, at present time there is no umbrella drug known for treatment of all forms of cancer. Applicants' disclose a therapeutic effect on humans. See specification @ page 5 last paragraph. Proof of such utility is required unless one of ordinary skill in the art would accept the utility statement as obviously valid and correct. Ex parte Ferguson, 117 USPQ 229. It is the examiner's position that the skilled artisan would not accept as correct a method directed to treating all forms of cancer as is presently claimed by applicants. Applicants' are not entitled to more than is reasonably enabled by their specification.

5. Claims 13,24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant methods encompass as yet unidentified and identified forms of cancer a description of which is not found in the specification.

Art Unit: 1625

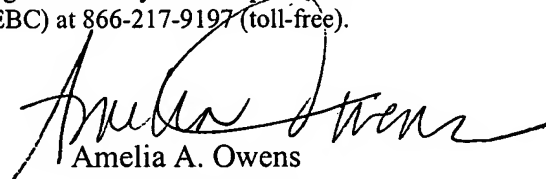
Claim Objections

Claims 14-20,25-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Amelia A. Owens
Primary Examiner
Art Unit 1625